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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,603	04/16/2004	James D. Thacker	8109.005.US	8050

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/825,603	Applicant(s) THACKER ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☒ Newly proposed or amended claim(s) *31-38* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *31-38*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-19,25-30,39-41*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1-19, 25-30 and 39-41 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated peptide consisting a nonapeptide as in SEQ ID NOs: 1-3 and 5 wherein the nonapeptide consists of up to three fatty acids are selected from the group consisting of stearic acid, arachidic acid and arachadonic acid, does not reasonably provide enablement for any isolated peptides having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:1-3 or 5, any isolated peptides comprising an nonapeptide or any isolated peptides comprising the SEQ ID NOs: 1-3 or 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims for the reasons set forth in the office action mailed 4/20/07.

Applicants' arguments filed on 5/29/07 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the amendments to the claims would obviated the rejection.

However, the amended claims still read on isolated peptide of any length comprising the SEQ ID NOs:1-3 or 5 with plurality of fatty acids upto 3.

The phrase "consists essentially of" in claims 1, 14 and 39 are open-ended. It expands the amino acid sequence of SEQ ID NO:1-3 and 5 to include additional non-disclosed amino acids. The SEQ ID NO:3 and SEQ ID NOs: 1, 2 and 5 are oligopeptides consist of 6 and 9 amino acids, respectively. The specification does not provide sufficient guidance as to which amino acid sequence can be added to the oligopeptides which retain a distinct functional property such as immunostimulating property of the SEQ ID NO:1-3 and 5.

The art recognizes that even minor structural differences among structurally related compounds or compositions can result in substantially different or deleterious biological activities. Ngo et al teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular, of record).

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since the amino acid sequence of a polypeptide determined its structural property, predictability of which amino acid fragment can retain the functional capabilities of the TGF-beta comprising polypeptide requires knowledge of, and guidance with regard to, which segments in the polypeptide's sequence contribute to its function.

Therefore, there is insufficient direction as to how to make any isolated peptide having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:3 any isolated peptides having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:1-3 or 5, any isolated peptides comprising an nonapeptide or any isolated peptides comprising the SEQ ID NOs: 1-3 or 5 which can be used as to whether such a desired effect can be achieved or predicted, as encompassed by the claims.

In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claims 1-19, 25-30 and 39-41 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the office action mailed 4/20/07.

Applicants' arguments filed on 5/29/07 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the amendments to the claims would obviated the rejection.

However, the amended claims still read on isolated peptide of any length comprising the SEQ ID NOs:1-3 or 5 with plurality of fatty acids upto 3. The phrase "consists essentially of" in claims 1, 14 and 39 are open-ended. It expands the amino acid sequence of SEQ ID NO:1-3 and 5 to include additional non-disclosed amino acids.

In light of discussion above, the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

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June 8, 2007

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